UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,991	12/14/2005	Fraser Harvie	PT-2655-US-PCT	9555

68622 7590 04/13/2009

NORMAN F. HAINER, JR.
SMITH & NEPHEW, INC.
150 MINUTEMAN ROAD
ANDOVER, MA 01801

EXAMINER	
LEWIS, RALPH A	

ART UNIT	PAPER NUMBER
3732	

MAIL DATE	DELIVERY MODE
04/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,991	HARVIE ET AL.	
	Examiner	Art Unit	
	Ralph A. Lewis	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29,50 and 62-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29, 50 and 62-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Obvious-type Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 29, 50 and 62-82 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-102 of U.S. Patent No. 6,620,185. Although the conflicting claims are not identical, they are not patentably distinct from each other because one of ordinary skill in the art would have found the present claims obvious in view of those already patented. More particularly, patented claim 35 sets forth the structure of a surgical instrument capable of carrying and receiving a suture with suture carrying device as required by currently pending claim 29. Moreover, previously patented claim 73 teaches use of a suture carrying device.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of

the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 29, 50 and 62-82 are rejected on the ground of nonstatutory double patenting over claims 1-58 of U. S. Patent No. 7,144,414 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter. More particularly, patented claim 1 sets forth the structure of a surgical instrument capable of carrying and receiving a suture with suture carrying device as required by currently pending claim 29.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Rejections based on 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 65, 68, 69, 74 and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 65, 68 and 69, the limitation that the "heating device comprises a thermistor" is misleading and inaccurate. As specified in claim 69 the thermistor(s) are sensors used to sense the temperature and are not the "heating device." Moreover, these claims lack critical limitations necessary for a functioning device – i.e. how do the termistors relate to what is being claimed.

In claims 74 and 75, there is no antecedent basis for "the method." The claims are dependent on apparatus claims. It is unclear if applicant is intending to claim the apparatus or claim a method.

Rejections based on Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29, 63, 67 and 70-73 are rejected under 35 U.S.C. 102(e) as being anticipated by Harvie et al (US 6,620,185).

Initially, it is noted that the present application does not claim priority back to the 09/604,387 application (6,620,185 patent) and that the earlier patent has a different inventive entity from the present application.

Harvie et al disclose a handpiece 52 having a cannulated tube 71 mounted on the handpiece 52 and having a tip through which a suture 70 is received, carried, and dispensed. The Harvie et al cannulated tube 71 includes a heating device 188 disposed therein. In regard to the "suture carrying device" limitation, Harvie et al indicates that the suture 70 may include a rigid shaped member 410 (Figure 21F) for increasing the resistance to the suture from being pulled out of the bone. In regard to claim 63, note depressions 69. In regard to claim 67, note tube 186 which inherently has some insulating properties.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29, 50, 62, 63, 67 and 70-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harvie et al (US 6,620,185).

In regard to claim 29, Harvie et al indicate that the Figure 21 sutures with suture carrying devices (i.e. anchors 410) are to be used with the surgical instrument, but fails to explicitly state that the suture carrying device 410 is carried within the cannulated tube 71 of the tool. One of ordinary skill in the art, however, would have found positioning of the suture carrying device within the cannulated tube along with the suture with which it is connected obvious as a matter of routine in carrying out the Harvie et al invention. In regard to claim 50, Harvie et al disclose a suture carrying device 412 (Figure 21G) that is slidable with respect to the suture. To have slid the 412 suture carrying device during use in order to properly position the anchor 412 would have been obvious to one of ordinary skill in the art. In regard to claim 61, providing a key member to prevent the Figure 21F anchor from getting twisted would have been obvious to one of ordinary skill in the art.

Claims 64 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harvie et al (US 6,620,185) in view of Doi et al (US 3,584,198).

Harvie et al fail to disclose the structure of heating element 188. Merely selecting a conventional off the shelf flexible foil heating element as that disclosed by Doi for the heating element 188 of Harvie et al would have been obvious to one of ordinary skill in the art as a matter of routine practice in carrying out the Harvie et al invention.

Claims 65, 68 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harvie et al (US 6,620,185) in view of Lavenuta (US 6,660,554).

Harvie et al fail to disclose the operation and control of heating element 188. The use of thermisters for controlling the heat output from such heaters is conventional to prevent over heating, note Lavenuta column 1, lines 22-35. Merely selecting conventional off the shelf thermisters as that disclosed by Lavenuta for controlling the heating element 188 of Harvie et al in order to prevent overheating would have been obvious to one of ordinary skill in the art as a matter of routine practice in carrying out the Harvie et al invention.

Applicant's Remarks

Applicant's remarks filed with the amendment of 12/18/2008 have been carefully considered and addressed in the grounds of rejection above.

Action Made Final

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication should be directed to **Ralph Lewis** at telephone number **(571) 272-4712.** Fax (571) 273-8300. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Cris Rodriguez, can be reached at (571) 272-4964.

R.Lewis
April 10, 2009

/Ralph A. Lewis/
Primary Examiner, Art Unit 3732